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EXAMINER	
SINGH, SATYENDRA K	
ART UNIT	PAPER NUMBER
1657	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/804,436	LYLES, MARK B.	
	Examiner	Art Unit	
	SATYENDRA K. SINGH	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 September 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15,19 and 20* is/are pending in the application.

4a) Of the above claim(s) *1-10* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11-15,19 and 20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *19 March 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's response and amendments to claims filed on September 2nd 2008 is duly acknowledged.

Claims 1-10 (non-elected invention of group I) remain withdrawn from further consideration.

Claims 16-18 were canceled by applicant's previous amendments.

Claims 11-15, 19 and 20 (group II, as currently amended) are examined on their merits in this office action.

The following contains new grounds of rejection necessitated by applicant's current amendments to pending claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the **second** paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 11-15, 19 and 20 (as currently amended) are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 11 (as currently amended) is confusing in the recitation of "*wherein the forming the suspension and dispersing steps occur after, but within hours of the initial formation of the area of skin lacking normal, healthy skin*" for several reasons. To begin with, the recitation of "after, but within hours of the initial formation of the area of skin lacking normal, healthy skin" does not set forth a clear time frame for the "suspension and dispersion ", because "after, but within hours" is essentially an infinite time period measured in hours rather than days or months. In addition, the exact timing of "initial

formation..." cannot be readily evaluated in most cases and therefore renders confusing the material intended. For example, the timing of "initial formation" of areas lacking normal, healthy skin, such as a wart, pimple, sunburn, inflammation, etc. cannot be accurately determined. It is noted that the "area lacking normal, healthy skin" in claim 14 "comprises a wound". However, even that term is not limiting as to the timing of "initial formation", as is the case in skin ulcers in diabetes, for example. It is also of interest to note that applicant has not provided a clear and unambiguous definition of what constitutes "normal, healthy skin" in this context or how to determine that it is "lacking". Appropriate explanation/correction is required.

Since, claims 12-15, 19 and 20 depend from the broader claim 11, they are also rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the **first paragraph** of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claim 11 (as currently presented) is/stands rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains **subject matter which was not described** in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 11 recites the limitation of "**forming a suspension consisting of a subject's isolated autologous stem cells** and a soluble medium", for which there is no support or description in the instant disclosure, original claims, drawing, or the examples

provided by applicants (see instant disclosure, pages 12-24, examples 1-5, in particular). The disclosure provided by applicants in the original claims (for example, claim 11 and 18 as originally presented), while providing the basis for a method of dispersing living cells comprising the step of suspending autologous cells that may further include stem cells, does not provide an explicit support (or exemplification or similar disclosure) for the step of "forming a suspension **consisting of** a subject's isolated autologous stem cells and a soluble medium", as currently presented by applicants. In addition, applicant's remarks (filed with the office on September 2nd 2008; see page 5, 1st paragraph, in particular) fail to point out an appropriate support for such a method step as recited in the instant claim 11.

The insertion of this limitation is **a new concept** because it neither has literal support in the as-filed specification by way of generic disclosure, nor are there specific examples of the newly limited genus which would show possession of the concept of the use of the step of "forming a suspension **consisting of** a subject's isolated autologous stem cells". This is a matter of written description, not a question of what one of skill in the art would or would not have known. The material within the four corners of the as-filed specification must lead to the generic concept. If it does not, the material is **new matter**. Declarations and new references cannot demonstrate possession of a concept after the fact. Thus, the insertion of said limitation is considered to be the insertion of new matter for the above reasons. Since, the claimed invention is not fully supported by the disclosure either in the narrative or generic or in the examples or in the original claims provided by applicants, the claimed limitation constitutes **a new matter situation**. Appropriate explanation/correction is required.

2. Claim 11 (as currently amended) is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. No basis or support is found in the present specification for "*wherein the forming the suspension and dispersing steps occur after, but within hours of the initial formation of the area of skin lacking normal, healthy skin"* in the context of *"a suspension consisting of a subject's isolated autologous stem cells*". Insertion of the limitation "wherein the forming the suspension and dispersing steps occur after, but within hours of the initial formation of the area of skin lacking normal, healthy skin" does not have support in the as-filed specification. The insertion of this limitation is a new concept because it neither has literal support in the as-filed specification by way of generic disclosure, nor are there specific examples of the newly limited genus which would show possession of the concept of the use of "wherein the forming the suspension and dispersing steps occur after, but within hours of the initial formation of the area of skin lacking normal, healthy skin" in the context of "a suspension consisting of a subject"s isolated autologous stem cells"

Careful examination of the specification indicates that only at page 10 of the specification, paragraph 2, are autologous cells provided to a wound at a disclosed time frame, and specifically "within hours to days following the formation of a wound by a variety of mechanisms". Nothing in this recitation envisions the use of "a suspension **consisting of** a subject's isolated autologous stem cells". This is a matter of written description, not a question of what one of skill in the art would or would not have known. The material within the four

corners of the as-filed specification must lead to the generic concept. If it does not, the material is new matter. Declarations and new references cannot demonstrate possession of a concept after the fact. Thus, the insertion of "wherein the forming the suspension and dispersing steps occur after, but within hours of the initial formation of the area of skin lacking normal, healthy skin" in the context of "a suspension consisting of a subject's isolated autologous stem cells" is considered to be the insertion of **new matter** for the above reasons. Appropriate correction is required.

Since, claims 12-15, 19 and 20 depend from the broader claim 11, they are also rejected under 35 U.S.C. 112, first paragraph for the reasons as discussed above.

Response to Applicant's arguments Regarding 112-first Rejection

Applicant argues the following (see response, page 5):

> "Written Description
> Claim 11 was rejected by the Examiner under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. Specifically, the Examiner argues that the specification fails to disclose "forming a suspension consisting of a subject's autologous stem cells in a soluble medium." The exact process need not be described because it is known in the art. (See MPEP §2163(II)(A)(2). An applicant need not disclose in detail, and preferably omits, that which is conventional or well known in the art.) For example, the Examiner's own cited art, U.S. Patent No. 6,497,875 issued to J. Michael Sorrell et al. ("Sorrell"), indicates that antibodies markers for human mesenchymal stem cells are known. (Col. 13, lines 18-20.) The use of antibodies in cell sorting, e.g. via fluorescence activated cell sorters (FACS), is well known. Thus at least on method of forming a suspension of stem cells in a soluble medium is readily apparent; the cells may be sorted by FACS using cell-specific antibodies, then suspended in a medium. Other methods of sorting stem cells known to the art are also encompassed by Claim 11. Accordingly, Applicant respectfully requests full allowance of Claim 11 as amended."

In response, it is noted that applicant's remarks (filed with the office on September 2nd 2008; see page 5, 1st paragraph, in particular) fail to point out an appropriate support for such a method step as recited in the instant claim 11. Moreover, this is a matter of written description, not a question of what one of skill in the art would or would not have known. The material within the four corners of the as-filed specification must lead to the generic concept. If it does

not, the material is **new matter**. The instant application (see discussion above) as originally filed fails to disclose the step of "forming a suspension consisting of a subject's isolated autologous stem cells and a soluble medium", and therefore said limitations are properly deemed as a new matter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claims 11-15, 19 and 20 (as currently amended) are/remain rejected under 35 U.S.C. 103(a) as being unpatentable over MARSHALL et al (US 6,479,052 B1; [A]) taken with the disclosure of COHEN et al (2000; [U]) and SORRELL et al (US 6,497,875 B1; [A2]).

Claims are generally directed to a method of dispersing living cells comprising: forming a suspension consisting of a subject's isolated autologous stem cells and a soluble medium; placing the suspension into a receptacle of an air-jet sprayer (having a nozzle orifice with a pore size sufficient to allow passage of the suspension without damage); and dispersing the suspension onto an area of skin of the subject lacking normal, healthy skin using the nozzle orifice of the air-jet sprayer, wherein the forming

the suspension and dispersing steps occur after, but within hours of the initial formation of the area of skin lacking normal, healthy skin. (see detailed recitations of instant claims 14-15, 19 and 20).

Marshall et al [A] disclose a method of dispersing autologous living cells on a skin wound (for example, keratinocytes, fibroblasts, etc.; see abstract, summary of the invention, column 2, 2nd paragraph; column 4, last paragraph, and claims, in particular) comprising suspending autologous cells in a soluble medium (see example 3, columns 12-13, in particular); placing the cells into a receptacle of **an air-jet sprayer** (having a nozzle orifice with a pore size sufficient to allow passage of cells without damage; see column 7-8); and dispersing the cells onto an area of skin of a subject (experimental animal such as Large White pig; see column 3, 1st paragraph, and example 3, in particular) lacking normal, healthy skin using the air-jet sprayer; wherein the **keratinocytes** (i.e. contained in **a cell suspension** having growth factors such as serum) are sprayed (with or without fibrin sealant, i.e. an adhesion factor) onto **a dermal graft** (such as Integra; example 3, column 13, in particular) or onto a tissue scaffold (such as fibrin matrix, or other types of biodegradable polymers; see columns 6-7, in particular). Furthermore, it is to be noted that Marshall et al [A] clearly suggest and disclose a method of dispersing living cells, wherein various types of autologous cells (including keratinocytes, fibroblasts, etc.) can be delivered **separately** onto a target (see column 3, 1st paragraph, and column 8, 1st and 2nd paragraphs, in particular), **or in combination** (i.e. co-dispersed or co-delivered) with other autologous cells, growth factors, bioactive agents, etc. (see column 6, lines 41-46, in particular).

Cohen et al [U] teach a method of dispersing living skin epidermal cells (in a suspension wherein the cells are isolated from the skin of groin area; see abstract, and page 1210, *Materials*

and Methods, in particular) comprising forming a suspension of **autologous epidermal cells** and a soluble medium (and that can further comprise growth factor such as fetal calf serum; antibiotics such as penicillin and streptomycin; see pages 1210-1211, right column, in particular); placing the cell suspension into a receptacle (see figure 1 for the device and parts, page 1208, in particular) of an air-jet sprayer (a commercial aerosolization device that uses compressed air, as shown in figure 1; having a nozzle orifice with a pore size sufficient to allow passage of cells without damaging dispensed cells); and dispersing the cells through the nozzle orifice onto an area of skin of a subject lacking normal, healthy skin (using pigs as experimental animals with full-thickness wounds on the back taken as area of skin lacking normal, healthy skin; see pages 1210-1211, in particular) using the air-jet sprayer; wherein the method further comprises growing a three-dimensional epithelial tissue from the cells in the area lacking normal, healthy skin (see table II-III, figures 3 and 5, and page 1212, in particular). In addition, it is to be noted that Cohen et al explicitly suggest an alternative method such as "to use the cells (i.e. subject's autologous epidermal cells that also contain stem cells) along with a dermal graft or dermal substitute" (see Cohen et al, page 1214, left column, 1st paragraph, in particular), and thus invite such modification and/or combination in the method of dispersing living cells onto an area of skin (even with unfavorable topography) of a subject lacking normal, healthy skin using an air-jet spray device, as recited by the instant invention.

However, a method according to claim 11, wherein the **suspension consists of autologous stem cells** and a soluble medium, is not explicitly exemplified by the referenced inventions of Marshall et al and Cohen et al.

Sorrell et al [A2] disclose the isolation, in vitro culture and expansion, and therapeutic use of **mesenchymal stem cells** (MSCs) in forming multilayer skin or dermal equivalent (see abstract, summary of the invention, column 8 and 9, in

particular), wherein suspension of autologous human MSCs are used in various tissue regeneration procedures including burn and wound/laceration management.

Therefore, given the fact that Marshall et al (taken with Cohen et al) explicitly disclose a method for aerosolized or spray delivery of living cells (using a suitable device such as an air-jet sprayer), including keratinocytes or epidermal cell suspensions (which are known in the art to contain stem cells) with or without fibrin sealant onto a target area such as skin wound, and further disclose spray delivery for fibroblasts (see column 2, 2nd paragraph, and column 3, 1st paragraph, in particular) and other suitable cells, it would have been obvious to a person of ordinary skill in the tissue-repair or regeneration art (at the time the claimed invention was made) to modify the method of Marshall et al (taken with Cohen et al) such that the method comprises the step of forming a suspension consisting of a subject's autologous stem cells (i.e. substituting a better functional equivalent; for their potential for enhancing tissue repair and regeneration which is well documented in the wound healing prior art) and a soluble medium, which is clearly suggested by the disclosure of Sorrell et al [A] for forming a dermal equivalent.

The specific limitation of separately delivering at least one different type of autologous cell suspension would have been a matter of routine arrangement and optimization of the method steps to an artisan of ordinary skill in the art, as evidenced by the fact that Marshall et al disclose individual delivery of autologous keratinocytes, and co-delivery of keratinocytes and fibroblasts (see column 5, 3rd paragraph, column 6, lines 41-46, in particular), and further suggest the fact that the device can be modified to provide more outlets, etc. (see column 8, 1st paragraph, in particular) depending on the need. In absence of any criticality attached (or demonstrated by applicants in the original disclosure as filed with the office) for the method step of "forming a

suspension consisting of a subject's isolated autologous stem cells and a soluble medium" that is dispersed onto the skin of the desired subject in need thereof, such method steps of using or dispersing autologous stem cells, alone or in combination with at least one other type of autologous cell suspension, would have been obvious to an artisan of ordinary skill in the tissue regeneration art when taking the combined disclosures of cited prior art into consideration, and accordingly would have had a reasonable expectation of success in modifying the method of dispersing living cells, as discussed above.

Given the detailed disclosures of the method steps of forming the cell suspension and delivering through the receptacle of an air-jet sprayer using the nozzle orifice by Marshall et al (taken in combination with the disclosure of Cohen et al), the limitations of "wherein the forming the suspension and dispersing steps occur **after, but within hours** of the initial formation of the area of skin lacking normal, healthy skin" would have been obvious to a person of ordinary skill in the clinical art for an optimal management of skin comprising wound, or for dispersing cells on an area of "skin lacking normal, healthy skin" in order to obtain benefits of using a freshly prepared cell suspension in the wound healing. Since, the claim limitation of "within hours" encompasses an infinite duration (when measured in terms of hours; see 112-second rejection above), and since, one of ordinary skill in the art would have known the benefits of using fresh cell suspension for skin wound management, such method steps, or order thereof would have been obvious to an artisan of ordinary skill in the clinical art at the time this invention was made.

Thus, the invention as a whole would have been *prima facie* obvious to a person of ordinary skill in the art at the time the claimed invention was made.

As per MPEP 2144.04, *Ex parte Rubin, 128 USPQ 440 (Bd. App. 1959) (Prior art reference disclosing a process of making a laminated sheet wherein a base sheet is first coated with a metallic film and thereafter impregnated with a thermosetting material was held to render prima facie obvious claims directed to a process of making a laminated*

sheet by reversing the ***order of the prior art process steps****). See also In re Burhans, 154 F.2d 690, 69 USPQ 330 (CCPA 1946) (selection of any order of performing process steps is prima facie obvious in the absence of new or unexpected results); In re Gibson, 39 F.2d 975, 5 USPQ 230 (CCPA 1930) (Selection of any order of mixing ingredients is prima facie obvious.).*

As per MPEP 2111.01, during examination, the claims must be interpreted as broadly as their terms reasonably allow. In re American Academy of Science Tech Center, F.3d, 2004 WL 1067528 (Fed. Cir. May 13, 2004)(The USPTO uses a different standard for construing claims than that used by district courts; during examination the USPTO must give claims their broadest reasonable interpretation.). This means that the words of the claim must be given their plain meaning unless applicant has provided a clear definition in the specification. In re Zletz, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989).

Response to Applicant's Arguments

Applicant's arguments filed with the office on September 2nd 2008 (as they pertain to the obviousness rejection of record) have been fully considered but they are not found to be persuasive for the following reasons of record.

In response to applicant's arguments (see response, pages 7-8, in particular) against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Regarding Marshall et al, applicants argue the following (see response, page 7):

> "…In particular, in Marshall, the suspension formation and dispersion steps were not performed until ten days after wound formation. (Col. 12, lines 10-59.) Marshall achieved results the authors considered satisfactory even with this delay; therefore there is no teaching or suggestion to administer cells with a shorter time of formation of an area of skin lacking normal, healthy skin. Additionally, Marshall does not teach or suggest the use of stem cells. Marshall achieved results the authors deemed satisfactory without stem cells, which are more difficult to harvest than the keratinocytes used by Marshall. Accordingly, there is no motivation to use stem cells in the methods disclosed by Marshall."

In response, it is noted that the claims as currently amended recite the limitation of "*wherein the forming the suspension and dispersing steps occur* ***after, but within hours*** *of the initial formation of the area of skin lacking normal, healthy skin*", which does not set forth a clear time frame for the "suspension and dispersion ", because "after, but within hours" is

essentially an infinite time frame measured in hours rather than days or months. In addition, the limitations of "the initial formation of skin lacking normal, healthy skin" (i.e. an undefined skin condition) in the context of "forming the suspension" or "dispersing the suspension" have not been clearly delineated with reference to time frame by applicants in the instant disclosure (see examples, 1-5, in particular). Moreover, it would be obvious to an artisan of ordinary skill in the clinical art to prepare and disperse the suspension containing living cells onto the desired area of skin wound (i.e. using a freshly prepared cell suspension in order to obtain the benefits of better wound healing properties of cells), and at the earliest possible time frame to avoid reduction in the beneficial activity of cells.

Similarly, the argument that Cohen et al do not teach the time frame for "forming the suspension" and dispersing steps (see response, page 7, last paragraph, in particular) as recited in amended claim 1, is not found to be persuasive because such arrangements and/or adjustments in time frame for the steps of forming cell suspension and dispensing on to the skin wound would have been obvious to a person of ordinary skill in the clinical art, and an artisan of ordinary skill would easily envision such changes in the methods of dispersing living cells as disclosed by Marshall et al (when taken with the disclosure of Cohen et al) for obtaining the benefits accrued by application of a fresher preparation of cells for an optimal skin wound healing, etc.

It is noted that the prior art of Sorrell et al has been relied upon in the obviousness rejection of record to demonstrate the fact that isolation, *in vitro* culture and expansion of human stem cells that can be used for tissue regeneration applications (such as burn and wound management) in the art has been known/disclosed, and an artisan of ordinary skill in the clinical art would have had a reasonable motivation of using them in the method of Marshall et al (when

taken with Cohen et al) for obtaining the obvious benefits of stem cell regeneration capabilities with a reasonable expectation of success. Thus, applicant's argument that "*The Examiner has failed to provide any logical reason, lacking hindsight, why these elements would be combined to produce the method of Claim 11*", are not found to be persuasive for the reasons as discussed above. The rejection of record is therefore properly made and maintained.

Pertinent Prior Art Not Relied Upon in Rejections

1. **ROLLAND et al (US Patent 7,144,729 B2; filed on Dec. 19, 2002),** Methods and compositions for tissue regeneration (discloses a method of dispersing isolated, living cell suspensions containing keratinocytes and fibroblast cells, or a mixture thereof onto a wound site using a suitable spray applicator, with or without fibrin glue, with or without scaffold, or dermal allografts, wherein the order of spraying the components can be readily modified or rearranged depending on the need; see abstract, summary of the invention, figures 4-6, column 7, 21-22, 25-26, and examples such as examples 16-17, in particular).

2. **GRANT I. et al.** The co-application of sprayed cultured autologous keratinocytes and autologous fibrin sealant in a porcine wound model, British J. of Plastic Surgery, 2002, 55: 219-227 (see summary, materials and methods, in particular).

3. **NAVARRO F.A. et al**. Sprayed keratinocytes suspensions accelerate epidermal coverage in a porcine microwound model, J. Burn Care Rehabil., 2000, 21: 513-518 (see abstract and introduction on page 513, Material and Methods, figure 1, and cited reference 8, in particular).

4. **NAVARRO F.A. et al.** Melanocyte repopulation in full-thickness wounds using a cell spray apparatus, J. Burn Care Rehabil., 2001, 22: 41-46 (see abstract on page 41, and materials & methods, in particular).

Conclusion

NO claims are allowed.

Applicants are advised that the prior art rejection under 35 USC 102(b) over COHEN et al [U] has been **withdrawn in view of the current claim amendments** that are deemed to constitute "**new matter**" as discussed above (see 35 USC 112, first paragraph rejection *supra*), and may be relied upon or re-instated in future depending upon further claim amendments during prosecution.

Furthermore, applicants should **specifically point out the support for any amendments made** to the disclosure, including the claims (MPEP § 714.02 and 2163.06). Due to the procedure outlined in MPEP § 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC §102 or 35 USC §103(a) once the aforementioned issue(s) is/are addressed.

Applicant is requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is requested in response to the office action.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SATYENDRA K. SINGH whose telephone number is (571)272-8790. The examiner can normally be reached on 9-5MF.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Satyendra K. Singh/
Examiner, Art Unit 1657

/Irene Marx/
Primary Examiner
Art Unit 1651